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HONORABLE SALVADOR MENDOZA, JR.

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:20-cv-00374-SMJ

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Noted: January 7, 2021
Without Oral Argument

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INTRODUCTION[1]

Plaintiff Jeremy Olsen is a Type I diabetic who also suffers from "brittle" diabetes with hypoglycemic unawareness. Mr. Olsen's diabetic condition resulted in damage to his kidneys, leading to kidney failure, and necessitating a kidney transplant. Both to address his underlying diabetes and to protect his transplanted kidney from damage as a result thereof, Mr. Olsen's treating physician prescribed a continuous glucose monitor (CGM). A CGM continuously tests glucose levels, alerts the user of out of range values, and, in Mr. Olsen's case, communicates with an insulin pump to automatically adjust insulin dosage. Incredibly, Mr. Olsen's claim for Medicare coverage for his CGM has been rejected by the Secretary on the grounds that a CGM is not "primarily and customarily used to serve a medical purpose" as set forth in CMS 1682-R.[2] ECF No. 23, ¶ 6. This non-sensical

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[1] Pursuant to LCivR 56(c)(1), Plaintiff is also filing a Statement of Material Facts Not in Dispute. The facts set forth here and in the Background section are only offered to help orient the Court. The limited facts identified in Plaintiff's Statement of Material Facts Not in Dispute are the only "material" facts necessary for the Court to grant summary judgment and they are undisputed.

[2] This is so even though the Council decision itself states: "Neither CMS in its referral, nor the Council in this decision, questions the appellant's medical

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position has already been rejected by four United States District Courts. Indeed, in three of those cases, the court found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorneys fees for having to litigate the issue.[3]

Beyond being non-sensical, the Secretary's decision is based on a Ruling issued, and applied to Mr. Olsen, in violation of law. Pursuant to 42 U.S.C. § 1395hh, before the Secretary can issue any rule, requirement, or policy that establishes or changes the rules regarding coverage, the Secretary must comply with the "notice and comment" requirements of the Medicare Act (which are more strict than those under the Administrative Procedure Act). Without complying with those requirements, the Secretary issued CMS Ruling 1682-R changing the regulatory requirement by holding that only "therapeutic" CGMs (*i.e.*, those that completely replace the need for finger sticks) would be covered going forward. ECF No. 23, ¶¶ 1 & 2.[4] That Ruling forms the basis for the denial in Mr. Olsen's

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condition, the judgment of his doctors, or the utility of the CGM to him." Decision at 7.

[3] Fees briefing in the fourth case is ongoing.

[4] All other CGMs (including the Medtronic MiniMed CGM) would be characterized as "precautionary" and not covered.

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case. That is a violation of the law. Mr. Olsen respectfully requests that this Court (1) hold that CMS Ruling 1682-R is not a valid ruling under the Medicare Act because it did not comply with the applicable notice and comment requirements, (2) hold that the Secretary's denial of Mr. Olsen's Medicare benefits is erroneous because it was based on the invalid CMS Ruling 1682-R, and (3) issue an Order requiring coverage and remand to the Council to effectuate the Court's decision.

I. BACKGROUND

1. Standard of Review

Pursuant to 42 U.S.C. § 405(g), the factual conclusions of the Secretary (if supported by substantial evidence) are conclusive. For all other questions, the Secretary's conclusions should be evaluated using any standard available under the Administrative Procedure Act (*e.g.*, arbitrary and capricious, abuse of discretion, contrary to law, etc.). *See, e.g.*, *Friedman v. Sebelius*, 686 F.3d 813, 826-7 (D.C. Cir. 2012).

2. Durable Medical Equipment

Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by examples. One specific example cited is "blood glucose monitors." The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is

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"durable medical equipment." *See* 42 C.F.R. § 404.202. Equipment is considered durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

3. Prior Litigation

The issue of whether a CGM qualifies as durable medical equipment has been litigated multiple times. In sum, the Secretary has refused to cover CGMs on the grounds: 1) that CGMs do not comply with the non-statutory/non-regulatory term "precautionary"; and/or 2) that CGMs do not serve a "primary medical purpose" (as opposed to the regulatory phrase "primarily … used to serve a medical purpose"). Those bases for denying CGM claims have been litigated in four district court cases.

In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018); *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018), and *Zieroth v. Azar*, Case No. 20-cv-172 (N.D. Ca. Sept. 22, 2020) the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" and was "precautionary" was erroneous, not supported by substantial evidence and/or was

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arbitrary and capricious and in each case, ordered the Secretary to provide CGM coverage. Three of those decisions are final and, absent an appeal, the fourth will be final by the time this motion is heard. Moreover, in three of those cases, the courts further found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorney fees for having to litigate the issue. Briefing on fees in the fourth case is on-going. In addition, the Secretary's own Civil Remedies Division concluded that the Secretary's claim that a CGM was not covered as "precautionary" did not meet the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18 (reversed on other grounds).

4. Notice and Comment Requirements

Pursuant to 42 U.S.C. § 1395hh(a)(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(emphasis added). The "paragraph (1)" referred to requires the Secretary to issue such rules, requirements or other statements of policy in the form of regulations.

Pursuant to 42 U.S.C. § 1395hh(b)/(c), proposed regulations must be published in the FEDERAL REGISTER and the public provided no less than 60 days

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to comment on the proposed regulations before the regulations may be published as final regulations.

In *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019), the Supreme Court held that the Medicare specific notice and comment provisions (rather than the APA's notice and comment provisions) apply to Medicare. *Id*. at 1809. Two differences between notice and comment under the Medicare Act and under the APA are: 1) the substantive/interpretive distinction under the APA does not apply to the Medicare Act; and 2) the Medicare Act requires 60 days of notice and comment rather than the 30 days under the APA. Thus, under § 1395hh, no rule, requirement, or statement of policy that establishes or changes the standard for paying for services/benefits can take effect until the notice and comment provisions have been complied with.

5. CMS 1682-R

Without prior notice and comment, on January 12, 2017, the Secretary issued CMS Ruling 1682-R. ECF No. 23, ¶¶ 1 – 2. There, the Secretary maintained that any CGM which did not completely replace finger sticks was "precautionary" and not covered. *Id*. The Secretary asserted that if the reading from a CGM sensor had to be confirmed with a fingerstick prior to making a treatment decision, the CGM was not "primarily and customarily used to serve a medical purpose." *Id*.

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Conversely, CGMs which do replace finger sticks the Secretary labeled "therapeutic" and considered covered. By its own terms, CMS 1682-R was effective as of the very date it issued – *i.e.*, January 12, 2017. *Id.* As described in the Council's decision, this is a "coverage policy for CGM's and ancillary equipment." [5]

6. Processing of Mr. Olsen's Claim

On March 14, April 18, and June 5, 2018, Mr. Olsen received supplies related to his CGM including sensors, an external transmitter, and water-proof tape. Mr. Olsen's claim for coverage for these items was rejected on July 13, 2018 on the grounds that "Medicare does not pay for this item or service."

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[5] On November 4, 2020, the Secretary published for notice and comment CMS 1738-P. *See* 82 Fed.Reg. 70358, 70398-404 (Nov. 4, 2020). As stated there, the Secretary is considering withdrawing CMS 1682-R and covering all CGMs. However, as indicated there, even if the proposed change is adopted, it would not take effect until April 1, 2021. Thus, the proposed policy will not affect this litigation. Further, as published, CMS 1738-P reflects the Secretary's intention to continue denying CGM claims for six more months on grounds that multiple courts have rejected, found not substantially justified, and ordered the Secretary to pay the beneficiary's legal fees for having to litigate.

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Thereafter, Mr. Olsen sought redetermination. Mr. Olsen's request for redetermination was denied on October 11, 2018 on the grounds that Mr. Olsen's CGM did not meet the definition of "therapeutic" in CMS 1682-R and, therefore, that coverage was barred. Thereafter, Mr. Olsen sought reconsideration.

Mr. Olsen's request for reconsideration was denied on December 18, 2018. Rather than alleged non-compliance with CMS-1682-R, Mr. Olsen's request was denied on the grounds that the file did not contain an order for the items at issue. Thereafter, Mr. Olsen filed an appeal that was assigned to ALJ Lambert.

After conducting a hearing in which CMS chose not to participate, on March 14, 2019, ALJ Marc Lambert issued a decision (ALJ Appeal No. 1-8237389961). ECF No. 23 ¶ 5. There, ALJ Lambert found that:

> Per a physician letter dated February 15, 2017, an insulin pump with a continuous glucose sensor was necessary to preserve the [kidney] transplant and reduce the risk of complications or worsening of existing conditions.

ECF No. 2, Ex. 6 at 2. Further, ALJ Lambert held that the claims should be covered because: 1) there was a signed order for the items in the file; and 2) the CGM works with the insulin pump, which is covered. *Id*. at 3.

Thereafter, CMS appealed ALJ Lambert's decision by "referring" it to the Medicare Appeals Council. In particular, CMS alleged that ALJ Lambert erred by

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not analyzing whether the Medtronic CGM qualified as "therapeutic" under CMS 1682-R and that the Medtronic CGM did not, in fact, qualify. ECF No. 23 ¶ 6.

On July 23, 2019, the Council issued a decision (M-19-1748) reversing ALJ Lambert's decision and denying coverage. *Id.* As an initial matter, the Council stated: "Neither CMS in its referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of his doctors, or the utility of the CGM to him." ECF No. 2, Ex. 7 at 7. Thereafter, the Council alleged that a CGM that does not completely replace finger sticks is "precautionary" and, therefore, does not "primarily and customarily [ ]serve a medical purpose." *Id.*

As articulated by CMS, though it "does not question … the utility of the CGM" to Mr. Olsen and, presumably the need for the CGM to protect Mr. Olsen's kidney transplant, the Secretary is entitled to deference in his claim that a CGM is not "primarily and customarily used to serve a medical purpose." *Id.* at 8-9. In the Secretary's view, the four courts to decide otherwise were wrong and the Article III courts should defer to the Secretary's greater wisdom.

A. DISCUSSION

The Secretary's denial of Mr. Olsen's claim should be reversed (and coverage ordered) because CMS 1682-R issued in violation of law for failing to comply with the applicable and requisite notice and comment requirements under the Medicare Act.

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A. The Denial Based on CMS 1682-R Should be Reversed

The denial of Mr. Olsen's claim should be reversed because CMS 1682-R issued in violation of law and alleged non-compliance with CMS 1682-R was the basis for the Council's denial of coverage

1. CMS 1682-R Issued In Violation of Law/ Denial Based on CMS 1682-R Is Unlawful

Without prior notice and comment (including publication in the FEDERAL REGISTER), CMS 1682-R issued on January 12, 2017, effective as of that very day. That was a violation of 42 U.S.C. § 1395hh. As stated in § 1395hh(2), "[n]o rule, requirement, or other statement of policy" that establishes or changes a standard concerning the scope of benefits, payment for services, etc. shall take effect unless promulgated by regulation issued in accordance with the notice and comment provisions. On its face, CMS 1682-R describes itself, *inter alia*, as a "statement[] of policy and interpretation." ECF No. 2, Ex. 9 at 1. Further, of course, by setting forth the standard of "precautionary" and "therapeutic" CGMs, CMS 1682-R purports to establish or change the standard concerning the scope of benefits, payment for services, or eligibility of individuals receiving a CGM. Thus, under § 1395hh, CMS 1682-R cannot "take effect unless it is promulgated by the Secretary by regulation" (including compliance with the notice and comment provisions). *See* 42 U.S.C. § 1395hh.

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Here, there is no genuine issue of material fact that the Secretary did not comply with the notice and comment provisions. Nothing was published in the FEDERAL REGISTER concerning proposed regulations, there was no opportunity for the public to comment, and there was no publication of final regulations. *See* 42 U.S.C. § 1395hh(b). Instead, in defiance of the statute, the Secretary simply issued a ruling establishing a new standard for benefits and, relying on that illegal standard, proceeded to reject claims (including Mr. Olsen's) on that basis. *See* ECF No. 2, Ex. 7 at 10 ("We, like the ALJs, are bound by CMS Rulings.", *citing* 42 C.F.R. § 405.1063(b)).[6] Thus, CMS 1682-R issued in violation of the law and the denial of Mr. Olsen's claim based on CMS 1682-R was also unlawful, should be reversed, and coverage ordered.

B. Mr. Olsen's Right to Object to CMS 1682-R Was Preserved

Pursuant to 42 C.F.R. § 405.1063(b):

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[6] In this regard, 42 C.F.R. § 405.1063(b) indicates that CMS Rulings are "published" and further indicates that "consistent with 401.108", they are binding on "all CMS components, [and] on all HHS components that adjudicate matters under the jurisdiction of CMS[.]" As set forth in 42 C.F.R. § 401.108(a), like 42 U.S.C. § 1395hh, it is contemplated that any such Rulings will be published in the FEDERAL REGISTER. Here, again, it is undisputed that that did not occur.

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> CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMD components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of that Social Security Administration adjudicate matters under the jurisdiction of CMS.

Indeed, in the decision at issue in this case, the Medicare Appeals Council explicitly stated that it was bound by CMS 1682-R. ECF No. 2, Ex. 7 at 10 ("We, like the ALJs, are bound by CMS Rulings."). Thus, because ALJs and the Council are bound by CMS Rulings, it would have been futile for Mr. Olsen to object to CMS 1682-R before either the ALJ or the Council and he did not do so.

It is fundamental that Mr. Olsen cannot waive arguments that both the ALJ and the Medicare Appeals Council are barred from addressing. That is, Mr. Olsen was not required to perform the futile act of asking either the ALJ or the Council to rule on the validity of CMS 1682-R (when both entities are barred from addressing that argument) in order to avoid waiver. *See, e.g., U.S. v. Kyle*, 734 F.3d 956, 962 n. 3 (9th Cir. 2013) ("a failure to raise a futile objection does not waive the objection."); *In re Two Appeals Arising out of San Juan DuPont Plaza Hotel Fire Litigation*, 994 F.2d 956, 961 (1st Cir. 1993) ("The law does not require litigants to run fools' errands."); *Northern Heel Corp. v. Compco Indust., Inc.*, 851 F.2d 456, 461 (1st Cir. 1988) ("The law should not be construed idly to require parties to perform empty acts or to engage in empty rituals."); *Kinslow v.*

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American Postal Workers Union, Chicago Local, 222 F.3d 269, 276 (7th Cir. 2000) (a statute "does not require a union member to perform futile acts in order to vindicate his rights."); *Miller v. Drexel Burnham Lambert, Inc.*, 791 F.2d 850, 854 (11th Cir. 1986) ("This circuit does not require a litigant to engage in futile gestures."). Thus, Mr. Olsen has not waived his right to object to CMS 1682-R.

In the *Zieroth* litigation, the district court found that a CGM was covered durable medical equipment and ordered coverage. Simultaneously, the district court held that the plaintiff had waived objection to CMS 1682-R by not raising the issue before the ALJ and the Council. In the district court's view, had the plaintiff raised the illegal issuance of CMS 1682-R before the ALJ and/or Council (though they were bound by its holding), that objection might have allowed for the development of the record. *Id.* at 4. Because the district court ruled in the plaintiff's favor on a different ground, appellate review of the decision as it relates to CMS 1682-R was precluded.

Respectfully, Mr. Olsen asserts that the *Zieroth* court was mistaken. No development of the record could have taken place given that the ALJ and Council were bound by CMS 1682-R. Indeed, given that the ALJ and Council were bound by CMS 1682-R, anything said by the ALJ or Council would have been dicta. Thus, because any objection to CMS 1682-R by Mr. Olsen would have been futile, Mr. Olsen did not waive objection to CMS 1682-R and this Court should

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hold the Secretary to the statute and not give effect to the very thing Congress has directed should not be given effect.

C. Coverage Should Be Ordered

Pursuant to 42 U.S.C. § 405(g) (fourth sentence):[7]

> The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

As detailed above, because CMS's referral and the Council's decision were limited to and premised on the alleged application of CMS 1682-R, there is no other proper basis for denying Mr. Olsen's claim. Thus, if the Court concludes that the Council was in error in this regard, then there is nothing further to be done by the Council and the Court should just issue an Order requiring coverage and remand to the Council to effectuate the Court's decision.

B. CONCLUSION

For the reasons set forth above, the Court should hold that CMS 1682-R is invalid, reverse the Secretary's denial of Mr. Olsen's claim, and order the Secretary to cover Mr. Olsen's claim.

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[7] As modified by 42 U.S.C. § 1395ff(b)(1)(A).

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Dated this 18th day of November 2020.

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By: *s/ Casey M. Bruner*

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CERTIFICATE OF SERVICE

I hereby certify that on the 18th day of November 2020,

1. I caused to be electronically filed the foregoing PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the following:

James.Bickford@usdoj.gov

2. I hereby certify that I have caused to be mailed by United States Postal Service the foregoing document to the following non-CM/ECF participants at the addresses listed below:

Jeffrey Blumenfeld
Lowenstein Sandler LLP
2200 Pennsylvania Avenue, NW, Suite 500E
Washington, DC 20037

3. I hereby certify that I have mailed by United States Postal Service the foregoing document to the following CM/ECF participants at the address listed below: **None.**

4. I hereby certify that I have hand-delivered the foregoing document to the following participants at the addresses listed below: **None.**

s/ Casey M. Bruner
Casey M. Bruner, WSBA #50168

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